UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC., et. al.

Defendants.

Case No. 4:21-cv-10312

Hon. F. Kay Behm

PLAINTIFF TRUTEK CORPORATION'S BRIEF IN RESPONSE TO DEFENDANT BLUEWILLOW BIOLOGICS, INC.'S BRIEF REGARDING MOOTNESS OF CASE

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

I. INTRODUCTION

Adjudication on the issues of patent validity and infringement should proceed. Although the Court has ruled that Trutek is not entitled to damages, and that BlueWillow's developmental vaccines are covered by the safe harbor provisions of 35 U.S.C. §271(e)(1), there remains a case or controversy due to BlueWillow's ongoing use of cationic surfactant adjuvant technology that constitutes real actions and sufficiently imminent infringement. Absent a declaratory judgement by this Court, there is nothing stopping BlueWillow from bringing the NanoBio® back to market. Trutek has met all the requirements for standing under Article III of the U.S. Constitution; the issue presented is not moot.

In addition, declaratory relief would be serve as an adequate remedy. Declaratory relief helps in clarifying the legal relationship between Trutek and BlueWillow and guides the behavior of the parties based on their established legal rights and duties.

II. FACTUAL BACKGROUND

In April of 2012, United States Patent No. 8,163,802 ("the '802 patent") entitled "Electrostatically Charged Nasal Application Product With Increased Strength" was issued to Plaintiff Trutek. In February of 2021, Trutek brought suit against Defendant BlueWillow, alleging that BlueWillow's product NanoBio®

Protect infringed upon the '802 patent. Trutek sought damages and injunctive relief. ECF 1.

On May 11, 2022, Trutek Filed a Motion for Leave to Amend the Complaint to add allegations of infringement as to BlueWillow's intranasal vaccines currently in development utilizing the cationic surfactant adjuvant technology covered under the '802 patent. ECF 28. The Court denied the motion, citing the safe harbor provisions of 35 U.S.C. §271(e)(1). ECF 32. Such provisions excuse infringement "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs[.]"

Thereafter, BlueWillow brought a motion *in limine* to exclude Trutek's damages-related theories and evidence (ECF 39) and later a Motion for Summary Judgment of no damages, injunctive relief, or jury trial. ECF 59. The Court granted the motion *in limine* in part, precluding Trutek from relying on undisclosed damages evidence, and found that because "the court's exclusion effectively precludes Trutek from seeking damages," BlueWillow's Motion for Summary Judgment with respect to no damages was moot. ECF 84. The Court denied BlueWillow's Motion for Summary Judgment with respect to injunctive relief and jury trial issues, choosing instead to order further briefing on the issues. *Id.* The Court directed the parties first to meet and confer about whether the injunctive relief and jury trial issues are moot

in light of the summary judgment order. *Id.* The parties did so but were unable to reach an agreement. Upon informing the Special Master of their impasse as directed, the Special Master requested additional briefing on the issue of mootness due to the Court's finding of no damages and BlueWillow's offer to stipulate to ceasing sales of the infringing NanoBio® Protect product.

III. LEGAL STANDARD

The bedrock of federal judicial power lies within the constitutional mandate of the "case or controversy requirement," an essential cornerstone enshrined in Article III of the U.S. Constitution. U.S. Constitution. Art. III. This doctrine ensures that federal courts adjudicate only live, genuine disputes between adverse parties, safeguarding against the rendering of advisory opinions. *Cty. of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979). Embedded within this requirement are fundamental principles dictating the necessity of an actual controversy, ripe for judicial determination, wherein parties possess standing and exhibit adverse legal interests. *Id.*

"The constitutional requisites under Article III for the existence of standing are that the plaintiff must personally have: 1) suffered some actual or threatened injury; 2) that injury can fairly be traced to the challenged action of the defendant; and 3) that the injury is likely to be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61, 112 S. Ct. 2130, 2136 (1992). A party without

standing may not proceed in federal court. Likewise, a party may not proceed with their action if the case or controversy becomes moot. The mootness doctrine is a limitation on the power of judicial review granted to the federal courts under Article III of the U.S. Constitution. "[A] case is moot when the issues presented are no longer 'live' or the parties lack a cognizable interest in the outcome." *Cty. of L.A. v. Davis*, 440 U.S. 625, 99 S. Ct. 1379 (1979), (quoting *Powell v. McCormack*, 395 U.S. 486, 498 (1969)).

IV. ARGUMENT

A. Limiting Relief to NanoBio® Protect Does Not Negate Available Relief

BlueWillow argues that NanoBio® Protect is the only accused product in the instant case. BlueWillow states, without basis, that "to the extent Trutek requests relief that is targeted to any other product, including BlueWillow's developmental vaccines, it must be denied." While BlueWillow's developmental vaccines are currently protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1), courts allow such protected activities to serve as evidence used to establish "meaningful preparation" to infringe. *Amgen, Inc. v. F. Hoffman-Laroche Ltd*, 456 F. Supp. 2d 267, 277-78 (D. Mass. 2006) (Defendant's "several clinical trials" and "… the filing of their Biologics License Application for CERA/PEG-EPO, *although protected by section 271(e)(1)*, are significant indicia of an "actual controversy.") Evidence of "meaningful preparation" to make, sell, or use an object subject to an infringement

charge can be used to show the potential for future infringement, so long as that future infringement is "real and imminent." *Amgen,* 456 F. Supp. 2d at 275 (D. Mass. 2006). While Trutek acknowledges that it cannot currently proceed with claims based on the developmental vaccines, the cationic surfactant adjuvant technology used to deliver those vaccines is nonetheless relevant to the present litigation as it is the same cationic technology at issue with the nasal product.

BlueWillow cites *Microsoft Corp. v. DataTern*, Inc., 755 F.3d 899, 911 (Fed. Cir. 2014) for the proposition that "the issues and products actually litigated define the scope of judgment." ECF 92. While the vaccines themselves were not subject to litigation, the technology providing for the delivery system for the vaccines goes to the heart of this proceeding. The fact that the vaccines are covered by the safe harbor provision does not remove the infringing cationic surfactant adjuvant technology from consideration. Furthermore, in *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013), the court allowed consideration of potentially infringing future designs that were not specifically before the court when deciding if voluntary cessation was adequate. Therefore, the fact that Trutek cannot bring a current claim for infringement based on the cationic surfactant adjuvant technology of the vaccines does not disappear evidence of the infringing technology underlying them. On the contrary, the availability of relief rests upon the use of that infringing technology in BlueWillow products.

B. Injunctive Relief Remains a Live Issue

BlueWillow claims that because they offered to execute a stipulation agreeing not to make, use, sell, offer to sell, or import NanoBio® Protect at any time in the future, Trutek's request for injunctive relief is now moot. ECF 92. Absent a declaratory judgement by this Court, there is nothing stopping BlueWillow from bringing the NanoBio® back to market. "A case might become moot if subsequent events make it absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 173, 120 S. Ct. 693, 700 (2000). Moreover, "a defendant claiming that its voluntary compliance moots a case bears the *formidable burden* of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 120 S. Ct. 693 (2000).

The crux of the case before the court is BlueWillow's use of Trutek's patented "electrostatically charged nasal application" technology. ECF 1. BlueWillow has used this technology in both NanoBio® Protect and its developmental vaccines.[1]

[1] BlueWillow's website describes the technology underlying their vaccines as follows: "BlueWillow's proprietary adjuvant platform, originally invented at the University of Michigan, utilizes oil-in-water emulsion droplets approximately 400nm in size combined with a cationic surfactant and stabilization buffer." *About Our Intranasal Adjuvant Technology* (Dec. 15, 2023), https://bluewillow.com/our-proprietary-technology-platform/. This is the same technology used to develop NanoProtect, the original name for NanoBio® Protect. *See Final Report: Reformulated NanoBio Nontoxic Hard Surface Sanitizer/Disinfectant Formulation To Inactivate and Kill B. Anthracis and Other Bioattack Pathogens,* EPA Grantee Research Project Results (Dec. 15, 2023),

The only evidence BlueWillow offers that their infringing behavior could not be "reasonably expected to recur" is their offer to stipulate. "[A] defendant cannot automatically moot a case by simply ending its unlawful conduct once sued." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013). In *Already*, the Court found that a covenant between the two parties to protect against future suits was sufficiently broad and "unconditional and irrevocable" that infringement could not be "reasonably expected to recur." *Id* at 93. More importantly, the covenant prohibited Nike from making *any* claim or demand and covered the current and past infringing designs at issue as well as any *future* designs. *Id.* The covenant covered the infringing designs broadly. Similarly, in *Deakins v. Monaghan*, 484 U.S. 193, 108 S. Ct. 523 (1988), the court found the case moot because pursuing a claim in court could not be resumed in "this or any subsequent action" and because it was entirely "speculative" that any *similar* claim would arise in the future. *Id.* At 200.

We can distinguish *Already* from the instant case because BlueWillow's offer to stipulate is nowhere near as comprehensive and covers just one infringing product, NanoBio® Protect. While it does purport to protect against future sale of the infringing product, again, it is limited to one product. Moreover, BlueWillow's offer

---

https://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract_id/6949/report/F. ("This technology is based on antimicrobial nanoemulsion technology developed by Dr. James Baker at the University of Michigan Medical School over a period of 6 years […] Commercialization of this technology, known as NanoProtect™[…]").

to stipulate does not negate "subsequent action" based on BlueWillow's infringement of the '802 patent. BlueWillow is currently developing other products that infringe upon the '802 patent in the same way as NanoBio® Protect: by using Trutek's patented cationic surfactant adjuvant technology. While those vaccines are presently covered by the safe harbor provision of 35 U.S.C. § 271(e)(1), they nonetheless showcase the utilization of the disputed technology, substantiating the claim of current and future infringement. BlueWillow is developing those vaccines with the intention of bringing them to market, where they will no longer be covered by the safe harbor. If BlueWillow's offer to stipulate covered not just the NanoBio® Protect product but the infringing technology at the core of both NanoBio® Protect and the developmental vaccines, it could be said to be comprehensive enough under the standard articulated in *Already* and protect against the subsequent action or similar claims the Court was concerned with in *Deakins*. Unfortunately, it does not.

Additionally, Trutek's concern with future infringement of a similar manner is not "speculative." BlueWillow is currently developing products that infringe on the '802 patent in the same way the NanoBio® Protect product does. BlueWillow intends to bring those products to market. Therefore, BlueWillow's future infringement is not speculative but imminent. Infringement on the '802 patent could be "reasonably expected to recur."

Ultimately, BlueWillow argues that because there is no injury to Trutek as a result of their offer to stipulate, the case has become moot. Standing requires that the party bringing suit "suffered some actual or *threatened* injury." *Lujan,* 504 U.S. at 560. Threatening injury is precisely what BlueWillow's continued use of the cationic surfactant adjuvant technology in developing products does. "When a 'party relies on potential infringement liability as a basis for injury in fact, but is not currently engaging in infringing activity,' […] the party 'must establish that it has concrete plans for future activity that creates a substantial risk of future infringement or [will] likely cause the patentee to assert a claim of infringement.'" *ABS Glob., Inc. v. Cytonome/ST, LLC*, 984 F.3d 1017 (Fed. Cir. 2021). BlueWillow's plans to bring their developmental vaccines to market are "concrete plans for future activity that creates a substantial risk of future infringement." *Id*. Because BlueWillow's offer to stipulate to not sell NanoBio® Protect in the future does not cover similar products that likewise infringe upon the '802 patent in the same way, there is potential infringement of which there are concrete plans to commit. As such, Trutek has met their burden of establishing injury for purposes of standing. Therefore, the issue of whether injunctive relief is available remains a live controversy under current law.

C. Trutek Has Standing to Maintain the Case

Standing requires that a party suffered an "actual or threatened injury" which can "fairly be traced to the challenged action of the defendant" and is "likely to be

redressed by a favorable decision." *Lujan*, 504 U.S. at 560-61. As established above, Trutek suffers a threatened injury due to the infringing products that are due to be brought to market and out of safe harbor protections. Trutek also suffered an injury with respect to NanoBio® Protect's infringement upon the '802 patent. The injury argument has been addressed in the previous section: Trutek's offer to stipulate not to sell NanoBio® Protect in the future does not negate the existence of a threatened injury. With respect to the causal relationship between BlueWillow's actions and the injury to Trutek, although BlueWillow does not admit to infringement of the '802 patent, Trutek has nonetheless provided adequate proof that BlueWillow is the cause in fact of Trutek's injury.

On the remaining issue of redressability, BlueWillow argues that no relief is available due to, among other things, the Court's ruling that Trutek is not entitled to damages. *See* ECF 84. Trutek's ability to receive damages in the instant case is inapposite to the issue of redressability as other relief remains open to Trutek in the form of injunctive and declaratory relief. With respect to injunctive relief, BlueWillow argues that their offer to stipulate to no longer selling NanoBio® Protect renders injunctive relief a useless remedy, but as established above, BlueWillow's offer is not sufficiently comprehensive enough to negate the possibility that direct or similar infringement would not recur. Therefore, injunctive relief remains a viable remedy that would redress Trutek's injury threatened by future infringement.

D. Trutek's Request for Declaratory Relief is Appropriate

In their Motion for Summary Judgment, Trutek requests a declaratory judgment with respect to patent validity and infringement. ECF 62. While it might not involve awarding damages or specific remedies, a declaratory judgment can be a crucial form of relief by providing certainty and guidance to the parties involved, thereby helping to prevent future disputes or legal actions.

BlueWillow argues that declaratory relief is inappropriate because there is no actual controversy between the parties. ECF 92. As established above, the issue of infringement is not mooted by BlueWillow's offer to stipulate and therefore remains a live issue. "To meet the controversy requirement in a declaratory judgment suit by a patentee against an alleged future infringer, two elements must be present: (1) the defendant must be engaged in an activity directed toward making, selling, or using subject to an infringement charge under 35 U.S.C. § 271(a), or be making meaningful preparation for such activity [reality]; and (2) acts of the defendant must indicate a refusal to change the course of its actions in the face of acts by the patentee sufficient to create a reasonable apprehension that a suit will be forthcoming [immediacy]." *Amgen, Inc. v. F. Hoffman-Laroche Ltd, 456 F. Supp. 2d 267, 277-78 (D. Mass. 2006),* (citing *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 764 (Fed. Cir. 1990).

As established in section A, BlueWillow is engaged in "meaningful preparation" of activities that will infringe upon the '802 patent in the same way NanoBio® Protect does. Further, BlueWillow has the ability to reproduce NanoBio® at any time should they chose. Additionally, the current development of vaccines the administration of which utilize Trutek's patented technology constitutes "meaningful preparation" even if those activities are currently protected by the safe harbor provisions of 35 U.S.C. § 271(e)(1).

The second prong of the controversy test articulated in *Amgen* requires that a defendant's "refusal to change the course" of its infringing acts "creates a reasonable apprehension that a suit will be forthcoming." *Id* at 275. BlueWillow has no intention of changing the course of developing products that utilize the infringing cationic surfactant adjuvant technology. Furthermore, its acts are sufficiently immediate. In *Telectronics Pacing Sys. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992), the court ruled that the defendant's acts were not sufficiently immediate to be considered an actual controversy because the defendant had only started clinical trials of the infringing product a few months prior to commencement of the suit and were thus "years away." *Id.* The Defendant also modified the product during clinical trials so there was no indication that the product would still infringe upon the relevant patent. *Id*. In contrast, the court in *Amgen* ruled that a product that was two years away from FDA approval was sufficiently immediate, explicitly distinguishing

this decision with the holding in *Telectronics*. *Amgen, Inc. v. F. Hoffman-Laroche Ltd*, 456 F. Supp. 2d 267, 277-78 (D. Mass. 2006). BlueWillow is far along in the developmental process. Moreover, BlueWillow couldn't have possibly modified the vaccines in the course of development so that they no longer infringe – the patented technology that is infringed upon by the vaccines is the vehicle with which the vaccine is administered. The infringing technology underpinning the vaccines cannot be extracted from the vaccine itself without destroying the vehicle with which the vaccine is administered. The facts of the case at hand suggest that BlueWillow's developmental vaccines would fall under the *Amgen* standard and be considered sufficiently immediate to establish controversy.

Since there is clearly a live controversy in the instant case, the Court should consider and issue a judgment with respect to patent validity and infringement. While courts do have discretion to issue declaratory judgments, there is a strong public interest in the finality of judgments in patent litigation. *Cardinal Chem. Co. v. Morton Int'l*, 508 U.S. 83, 100, 113 S. Ct. 1967, 1977 (1993). In *Sinclair & Carroll Co.* v. *Interchemical Corp.*, 325 U.S. 327, 89 L. Ed. 1644, 65 S. Ct. 1143 (1945), the court approved of the District Court's decision to consider the question of validity even though it had found that a patent had not been infringed. In *GE Co. v. Nintendo Co., LTD.*, 179 F.3d 1350, 1356 (Fed. Cir. 1999), the court went as far as to say that without addressing the issue of patent validity, we deprive the 'patentee of the

appellate review that is a component of the one full and fair opportunity to have the validity issue adjudicated correctly.

E. Additional Unresolved Matters Necessitate Court Consideration

Plaintiffs have a pending Motion for Reconsideration before the Court, addressing a factual discrepancy present in the record.[2] ECF 89. This motion seeks to rectify an essential factual error that has significant bearing on the availability of pre-suit damages. In their motion, Trutek states "that the court erred in granting summary judgment with respect to pre-suit damages because judgment was based on a mistake of fact, the correction of which would alter the outcome of the summary judgment order in that respect." ECF 89, p. 1-2. The Court has yet to render an opinion on this matter. Should the Court rule that a factual error was made, pre-suit damages remain available for Trutek to pursue. Without resolution of this matter, the factual dispute at the heart of this motion retains its status as a live matter and cannot be rendered moot.

Moreover, should the Court rule that it made a mistake of fact that re-opens the availability of pre-suit damages, Plaintiffs can rely upon the "sales document"

[2] The error pertains to the 35 U.S.C. 287(a) marking statute. In order to prove that Plaintiffs do not comply with the marking statute, Defendants presented a product from an alleged Trutek licensee that is unmarked. The Court relied upon Defendant's presentation of this product to determine that BlueWillow had met its burden of production, shifting the burden of proving compliance with 35 U.S.C. 287(a) to Trutek. This reliance was misplaced, as the product presented was not that of a Trutek licensee. See ECF 89.

introduced by BlueWillow during discovery to establish a reasonable royalty under 35 U.S. Code § 284. ("Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court.") In granting BlueWillow's Motion *in limine* to exclude Trutek's damages related theories and evidence, the court noted that the "exclusion does not apply to the sales document and its financial data for sales of the accused NanoBio product." (ECF 84, p. 35). Trutek is therefore still entitled to use the document and its data to prove pre-suit damages.

Importantly, the "sales document" includes data on sales commissions and fees. Sales commissions and fees have been used by courts to establish a reasonable royalty. In *Spectralytics, Inc. v. Cordis Corp.*, 649 F.3d 1336, 1346 (Fed. Cir. 2011), the court held that a commission paid to sales representatives to procure business relationship with distributor was relevant to hypothetical negotiation between patentee and competitor for a royalty. BlueWillow's "sales document" provides data on the amount paid to sales representatives of the NanoBio® Protect product. This data represents a percentage of revenue that BlueWillow was willing to forgo to ensure the sale of its NanoBio® Protect product and thus can be used as a basis for a hypothetical negotiation that would have yielded a reasonable royalty to Trutek for the licensing of their patented product. *See Ga.-Pacific Corp. v. United States*

Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970). Therefore, should the court find that it made a factual mistake with respect to adjudicating the issue of pre-suit damages, the "sales document" provided by Defendants yields enough data to determine a reasonably royalty and thus a damages calculation.

V. CONCLUSION

Because there remains an actual controversy between the parties that is not rendered moot by BlueWillow's offer to stipulate not to sell NanoBio® Protect, and because the Court has yet to opine on the Motion for Reconsideration, Trutek's case remains a live controversy and should not be dismissed.

Dated: December 21, 2023

Respectfully submitted,

/s/ *Stanley H. Kremen*
Stanley H. Kremen, Esq.
4 Lenape Lane
East Brunswick, NJ 08816
Tel: (732) 593-7294
Fax: (732) 312-5218
shk@shk-dplc.com

/s/ Keith Altman
Keith Altman, Esq. (P81702)
THE LAW OFFICE OF KEITH ALTMAN
33228 West 12 Mile Road, Suite 375
Farmington Hills, MI 48334
Tel: (987) 987-8929
keithaltman@kaltmanlaw.com

Attorneys for Plaintiff, Trutek Corp.

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC., et. al.

Defendants.

Case No. 4:21-cv-10312

Hon. F. Kay Behm

CERTIFICATE OF SERVICE

I certify that on December 21, 2023, I served the foregoing document upon all parties/counsel of record by filing copies of same using this Court's CM/ECF System.

/s/ *Keith Altman*
Keith Altman, Esq.